

**BOARD OF REGISTRATION IN PHARMACY  
PHARMACY BOARD MEETING MINUTES  
TUESDAY, MAY 28, 2002  
239 CAUSEWAY STREET, ROOM 206  
BOSTON, MASSACHUSETTS  
02114**

The meeting was called to order by President Harold B. Sparr 9:15 a.m.

The following Board members were present: Harold B. Sparr, R.Ph., MS, President, Donna M. Horn, R.Ph., Secretary, Dan Sullivan (10:50 a.m.), R.Ph., Karen M. Ryle, R.Ph., MS, James T. DeVita, R.Ph., Dr. Robert P. Paone, R.Ph., Pharm. D., and Marilyn M. Barron, MSW, Public Member.

The following Board staff were present: Charles R. Young, R.Ph., Executive Director, Susan Manning, J.D., Administrative Board Counsel, James D. Coffey, R.Ph., Associate Director, James C. Emery, C.Ph.T., Healthcare Investigator, Alan Van Tassel, Healthcare Investigator, and Leslie S. Doyle, R.Ph., Healthcare Supervisor and Investigator.

**AGENDA ITEMS**

**1. 9:15 a.m.**

**Call to order: Investigative Conference & Business Meeting**

Lynn Community Health Center 340B Program Discussion  
Lynn Community Health Center, 269 Union Street, Lynn, Massachusetts  
The center will be represented by Executive Director, Lori Berry.

The purpose of the meeting was to continue discussion regarding a proposal by Lynn Community Health Center proposal for the Board to waive its policy of precluding the co-location of two licensed pharmacies as such relates to 340B Program considerations.

Present for discussion:

Lynn Community Health Center: Ex. Dir. Lori Berry and pharmacy consultant Sophie McIntyre, R.Ph.

Eaton Apothecary's Manager of Record; David Dumouchel

DPH/DCP: Michael Mozzer

DMA: Paul Jeffrey

Lori Berry advised the Board that at the May 07, 2002 Board meeting she was under the assumption that the existing pharmacy grant program would end in May 2002.

However, Berry stated that the clinic recent received a reprieve being that additional grant funding was extended through September 30, 2002.

The Board addressed financial implications related to the proposed pharmacy.

Lori Berry advised the Board that the goal of the pharmacy proposal was not to make a profit but rather to provide quality pharmaceutical care to patients in need and to offset related clinic financial losses. Berry stated that the proposed pharmacies patient payer mix was on or about 40 % uninsured with commercial insurance, 40% Medicaid, 10% miscellaneous and 10% Medicare per SSI.

Paul Jeffrey encouraged the Board to look favorably upon the pharmacy proposal because it would provide both pharmaceutical care services to patients in need and would save monies for both DMA and the commonwealth. Mr. Jeffrey stated that a pilot project was underway at DMA related to similar 340b issues with a family health center. Jeffrey commented that in such a non-traditional structured business arrangement DMA must also issue two (2) contracts/certifications to one pharmacy entity.

Mr. Dumouchel informed the Board that his business operation could separate out all billings with regard to both the retail and proposed clinic pharmacy operation.

Lori Berry advised the Board that an onsite pharmacy at the medical clinic was a hardship because of lack of space in the medical clinic and due to significant construction costs. Berry stated that she was hopeful the Board would consider a pilot and or demonstration project.

Lori Berry offered to the Board the opportunity to review the proposed pharmacy business records for 1 year.

Board counsel Susan Manning advised the Board that the eligibility for the "uncompensated care pool" is defined by the state legislature.

A **Motion** was made by Harold Sparr to take under advisement. The motion was seconded by Karen Ryle. The motion carried.

**2. 9:50 a.m. to 10:10 a.m.**

**In the matter of David L. Lambert, Registrant (License Number 22821 / Expiration on or about 12/31/1996).**

The purpose of the conference was to provide the Board with an opportunity to meet with the Registrant (Lambert) pursuant to a request for pharmacist reinstatement.

**Recused:** Jim DeVita

Registrant: David L. Lambert  
CVS Representative: Dick Sharp, Regional Healthcare Manager

A **Motion** was made by Donna Horn to discuss the matter with the Registrant (Lambert) in executive session. The motion was seconded by Bob Paone. The motion carried unanimously.

A **Motion** was made by Harold Sparr to move out of executive session. The motion was seconded by Donna Horn. The motion carried unanimously.

**Re-discussion:** (2:30 p.m.) The Registrant (Lambert) returned to the Board in the afternoon with complaint CE's in hand for 1997 & 1998. Mr. Lambert obtained the duplicate CE's this day from Northeastern School of Pharmacy. A Motion was made by Bob Paone to offer the Registrant (Lambert) an Advisory Letter with stipulation that reinstatement would be granted by the Board after the Registrant passed MPJE and settled past due licensing fees. (no additional CE's required). The motion was seconded by Dan Sullivan. The motion carried unanimously.

**3. 10:10 a.m. to 10:50 a.m.**

**Investigative Conference: DS-02-070 & PH-02-070**

**In the matter of Lincoln Discount Drugs, 161 East Main Street, Milford, MA 01757 (Permit # 21238) and Registrant, Michael G. LaCava, R.Ph., (License # 24404).**

The purpose of the conference was to discuss a complaint submitted by the Department of Public Health (DMR) alleging the failure to fill a prescription properly. The complainant alleged that on or about September 23, 2001 the Registrant dispensed Minocin 50mg rather than Mysoline 50mg tablets as prescribed while employed at Lincoln Discount Drugs, 161 East Main Street, Milford, Massachusetts.

Investigator: Leslie S. Doyle  
Complainant: Not present.  
Registrant: Michael G. LaCava  
Lincoln Discount Drugs Manager of Record: Richard Aronovitz

The Registrant (LaCava) advised the Board that he had not previously appeared before the Board with regard to a disciplinary action. The Manager of Record, (Aronovitz) informed the Board that he had appeared before the Board with regard to another complaint matter.

Investigator Leslie S. Doyle reviewed her report of investigation with the Board.

The Registrant (LaCava) acknowledged responsibility for the medication error. LaCava stated that he was new to the retail pharmacy position when the incident occurred. LaCava said that he did not work well with one of the pharmacy technicians

on staff. LaCava said that he believed that this technician pulled the medication at issue from the pharmacy shelf on the incident date. However, LaCava said that he was the checking and or verification pharmacist with regard to the error. LaCava stated that perhaps he was distracted during the final product validation process.

LaCava said that he was a 1999 graduate of MCPHS and primarily had experience in hospital pharmacy practice. LaCava stated that his hospital background made him more familiar with generic medication names rather than brand names.

The Registrant (LaCava) informed the Board that he did speak to a nursing home representative about the error and apologized for the incident.

LaCava informed the Board that he had no evidence of calendar year 2000 CE certificates of completion because of a recent divorce. LaCava stated that he allegedly completed proper CE's for year 2000 and could attempt to obtain duplicate copies of such certificates for the Board to review. LaCava represented that he was responsible for coordinating CE programs while employed at Value Pharmacy in West Boylston, MA and therefore could speak to Karen Burton about obtaining duplicate CE certificates.

The Manager of Record, Richard Aranovitz, advised the Board that the initials of "DAH" appear on pharmacy records as the dispensing and or verification pharmacist of record because pharmacist David Hoffman corrected the medication error and therefore his initials overrode LaCava's.

**Board Decision:**

A **Motion** was made by Harold Sparr to take the matter under advisement in order to provide the Registrant (LaCava) with an opportunity to produce proper evidence of CE compliance. Sparr advised Mr. LaCava that the requested CE records were to be submitted to the Board for review prior to June 25, 2002 Board meeting. The motion was seconded by Donna Horn. The motion carried unanimously.

**4. 11:00 a.m. to 11:55 a.m.  
OxyContin® Discussion.**

The Board continued its discussion of OxyContin® related matters to include follow up regarding a May 16, 2002 meeting with the Executive Office of Public Safety.

Board counsel Susan Manning provided an overview of the Board's meeting with the Executive Office of Public Safety.

The following public members in attendance chose to provide comments for the Board to consider:

Pain management specialist, Dr. Gerstein, of the Harvard Medical School stated that he primarily prescribes Methadone and or OxyContin® for chronic pain patients. Dr. Gerstein represented that only 5% of insurance companies claims data indicate that patients on OxyContin have a cancer diagnosis.

William Cardarelli of Harvard Vanguard Medical Associates stated that OxyContin® has been removed from the formulary at the HMO's 14 Massachusetts pharmacies. Cardarelli stated that no problems have developed to date as a result of such action.

Paul Cutroni of Blue Cross Blue Shield expressed concern for the responsibility of pharmaceutical care in circumstances where OxyContin® prescriptions may be dispensed by a central fill pharmacy located out of state.

Michael J. Mozzer of DPH/DCP stated that Dr. Gerstein's comment was well founded concerning the notion that the physician does not send a patient out to a pharmacy of the patient's choice with an OxyContin® prescription without first consulting with the pharmacy regarding the availability of the medication. Mozzer stated that DPH/DCP was working to establish appropriate prescribing guidelines for OxyContin®.

A representative from the American Cancer Society (ACA) stated that she had no official comment but noted that ACA Regional Director, Jose Vincente planned to provide formal comments to the Board on June 11, 2002.

Purdue Representative, Mary Kayson informed the Board that the company was working with the FDA with regard to OxyContin® reformulation efforts. Kayson said that related clinical research trials were underway with Naltraxone but that trial related to intravenous rather than oral dosage forms of OxyContin®. Kayson said that she would arrange for a Purdue clinical research representative to speak with the Board on June 11, 2002 if requested.

Jim DeVita commented that his readings on the OxyContin® reformulation matter indicated that the FDA process would take on or about 3 to 5 years to complete pending positive trials.

Karen Ryle stated that the Board expressed their concern to EOPS Secretary Jajuga regarding the alleged state budgetary fall short that called for the closing of certain methadone clinics. Sec. Jajuga responded he was hopeful that such closings could be avoided.

**A Motion** was made by Harold Sparr to offer an invitation to the Walgreens Pharmacy corporate office to address the Board at the June 11, 2002 meeting with regard to its alleged plans to offer an alternative distribution system for OxyContin® in Massachusetts. The motion was seconded by Bob Paone. The motion carried.

5. 12:00 p.m. to 12:30 p.m.

**Investigative Conferences: In the matter of:**

**PH-01-110: Registrant, Anita Berzins, R.Ph., (License #18160)**

**PH-01-112: Registrant, Elizabeth A. Bennett, R.Ph., (License #23922)**

**PH-01-125: Registrant, David C. Beck, R.Ph., (License #17515)**

**PH-01-107: Registrant, Joseph R. Asselin, R.Ph., (License #11973)**

**PH-02-040: Registrant, Stephen C. Connors, R.Ph., (License #16819)**

The purpose of the conference was to discuss complaints submitted by the Board alleging the failure to comply with requisite continuing education requirements as set forth at 247 CMR, Section 4.03.

Investigators Warren, Doyle, Emery and Van Tassel reviewed their reports of investigation with the Board.

**PH-01-110: Registrant, Anita Berzins, R.Ph., (License #18160)**

The Registrant (Berzins) acknowledged CE deficiencies for calendar year 2000. Berzins stated she was short 11 CE's due to personal family issues. The Registrant also stated that she placed a hold on her in mail in Newton for 1 month because moving to a new address. Berzins completed 18 CE's for calendar year 2001.

A **Motion** was made by Jim DeVita to offer an Advisory Letter to the Registrant (Berzins) for the failure to comply with requisite CE requirements with the stipulation that Berzins complete 33 CE in 60 days of which at least 3 CE's shall be live and 6 CE's shall be law. The motion was seconded by Bob Paone. The motion carried.

In addition, a **Motion** was made by Bob Paone to offer the Registrant (Berzins) an Advisory Letter for the failure to appear to the December 04, 2001 Board Investigative Conference regarding the same matter. The motion was seconded by Karen Ryle. The motion carried.

**PH-01-112: Registrant, Elizabeth A. Bennett, R.Ph., (License #23922)**

Assoc. Director, James D. Coffey advised the Board that the Registrant (Bennett) contacted the Board prior to the conference and advised the Board that she did not plan to attend the conference and requested that the Board retire her license.

A **Motion** was made by Jim DeVita to refer the matter to Board Counsel to offer the Registrant (Bennett) a retirement agreement. The motion was seconded by Karen Ryle. The motion carried.

**PH-01-125: Registrant, David C. Beck, R.Ph., (License #17515)**

The Registrant (Beck) failed to appear for the conference scheduled for 12 p.m.

Thereafter, the Registrant appeared for the conference to discuss the matter following the Boards lunch break (1:30 p.m.).

Assoc. Director, James D. Coffey provided the Board with an overview of the Beck CE matter.

The Registrant (Beck) advised the Board that he had no evidence of CE's to provide the Board for calendar years 1999 & 2000. Beck informed the Board that he believed he completed the CE's but it was a problem related to improper record keeping.

Beck informed the Board that he is currently the Manager of Record for Wayland Apothecary.

A **Motion** was made by Bob Paone to offer the Registrant (Beck) an Advisory Letter for the failure to complete requisite CE requirements for calendar years 1999 and 2002 with stipulations to include; 1) the Registrant (Beck) shall provide the Board with a written statement regarding his failure to attend the related December 04, 2001 Board conference, 2) The Registrant (Beck) shall forward the Board his original certificates of CE completion for calendar year 2001 for review, 3) the Registrant (Beck) shall complete 90 penalty hours of CE for 1999 & 2000 of which at least to 30 CE's shall be live and 12 CE's shall be law and 4) the Registrant (Beck) shall pass the MPJE examination for Massachusetts. The motion was seconded by Donna Horn for Discussion purposes.

The Board entertained discussion on the matter.

The motion did **not** carry.

A **Motion** was made by Harold Sparr to offer the Registrant (Beck) a Consent Agreement with stipulations to include; 1) the Registrant (Beck) shall be issued a two (2) week Suspension which shall begin within 90 days following a signed agreement, 2) the Registrant (Beck) shall be placed upon probation for one (1) year, 3) the Registrant (Beck) shall pass the MPJE examination for Massachusetts, 4) the Registrant (Beck) shall complete thirty (30) hours of CE in 30 days and 5) the Registrant (Beck) shall file a Change of Manager application with the Board complete with a copy of a controlled substance inventory within five (5) business days. The motion was seconded by Karen Ryle.

Vote: In support: Harold Sparr, Karen Ryle, Dan Sullivan, Donna Horn, Marilyn Barron, Opposed: Bob Paone and Jim DeVita. The motion carried.

It should be noted that Donna Horn referenced the fact that the Board needs evidence of complaint CE from the Registrant (Beck) with regard to the terms described above.

**PH-01-107: Registrant, Joseph R. Asselin, R.Ph., (License #11973)**

Assoc. Director, James D. Coffey advised the Board that the Registrant (Asselin) contacted the Board prior to the conference and advised the Board that he did not plan to attend the conference and requested that the Board retire his license due to the circumstances described in his letter of response to the Board.

A **Motion** was made by Jim DeVita to refer the matter to Board Counsel to offer the Registrant (Asselin) a retirement agreement. The motion was seconded by Bob Paone. The motion carried.

**PH-02-040: Registrant, Stephen C. Connors, R.Ph., (License #16819)**

The Registrant (Connors) advised the Board that he was compliant with CE's being that he forgot to forward Investigator Doyle 1 CE from an MPHA CE program. The Board reviewed the original CE certificates and determined that the Registrant was compliant.

A **Motion** was made by Bob Paone to Dismiss the matter against the Registrant (Connors). The motion was seconded by Karen Ryle. The motion carried

**6. 12:30 p.m. to 1:30 p.m.**

**Lunch**

**7. 1:30 p.m. to 2:00 p.m.**

**Applications for a New Pharmacy \*Waivers**

**In the matter of Parental Infusion Associates LLC, D.B.A. "Clinical IV Network", 102 G Street, Unit 4, Seekonk, MA 02771**

**The applicant was represented by the proposed Manager of Record, Karen A. Travers, R.Ph., (License No. 19115), RN (License No. 211481) and Counsel Thomas S. Crane.**

The purpose of the meeting was to discuss the merits of a waiver petition for a new pharmacy wherein, Clinical IV Network requests that the Board consider waiving the following regulatory provisions: 247 CMR;

Karen Travers, the proposed Manager of Record, advised the Board that "Clinical IV Network" was primarily an intravenous business that focuses upon servicing the needs of hospice patients. Travers stated that the business employs registered nurses, pharmacists, delivery drivers and management personnel.

Travers stated the pharmacy department requested waivers from the Board because the pharmacy did not plan to service walk in patient needs but rather to deliver medications directly to hospice residences. Travers described to the Board the compelling public interest that would be served by granting Clinical IV Network the waivers under consideration. Travers said that the pharmacy would supply only

intravenous medications to patients not oral medications.

Travers stated that the proposed business hours of the pharmacy were per diem until such time that the business operation picked up. Travers said that the overall square footage of Clinical IV Network was on or about 1500 square feet. Travers stipulated the pharmacy department was separately alarmed.

Travers stated that Clinical IV Network provides for 24 hour on call staff nurses, pharmacists and delivery personnel. Travers represented that Clinical IV Network will provide pharmacy-counseling services for its customers. Travers said that she will amend the Board application because the pharmacy does plan to carry Schedule II-VI controlled substances.

Travers informed the Board that the pharmacy would be utilizing self-venting class 100 sterile product hoods. Travers stated that the vast majority of intravenous medications prepared by the pharmacy would be stored in a refrigerator prior to delivery. Travers said the pharmacy was equipped with a pass-through area for central intravenous admixture service.

6.01 (6) (a) (8): whenever applicable, at least one bound book for recording sales of controlled substances which may be sold over-the-counter without a prescription;  
Approved:   X        Denied:       

6.01 (6) (a) (9): whenever applicable, at least one book for recording sales of alcoholic beverages and signatures of the purchasers of these beverages.  
Approved:   X        Denied:       

6.02 (4): The pharmacy or pharmacy department shall maintain on the premises at all times a sufficient variety and supply of medicinal chemicals and preparations which are necessary to compound and dispense commonly prescribed medications in accordance with the usual needs of the community.  
Approved:   X        Denied:       

9.07 (3) (c): A sign of not less than 11 inches in height by 14 inches in width shall be posted in a conspicuous place, adjacent to the area where prescriptions are dispensed, informing customers of their rights, pursuant to 247 CMR 9.00 and to M.G.L. c. 94C, § 21A, to counseling by a pharmacist where their prescription was filled. Said sign shall read, in letters not less than ½" in height: "Dear patients, you have the right to know about the proper use of your medication and its effects. If you need more information please ask the pharmacist."  
Approved:   X        Denied:       

9.01 (15): Unless otherwise provided for by law, a pharmacist shall not limit his or her services to a particular segment or segments of the general public.

9.01 (16): A pharmacist shall not refuse to compound customary pharmaceutical preparations except upon extenuating circumstances.

Approved:  X  Denied:

Overall Application for new pharmacy licensure: Approved:  X  Denied:

A **Motion** was made by Donna Horn to approve both the application and waivers as submitted subject to a compliant inspection. The motion was seconded by Dan Sullivan. The motion carried unanimously.

**8. 2:00 p.m. to 2:40 p.m.**

**Investigative Conference: DS-02-059 & PH-02-075**

**In the matter of Costco Pharmacy #308, 71 Second Avenue, Waltham, MA 02154 (Permit #2279) and Registrant, Ronni Yellen, R.Ph., (License # 18596).**

The purpose of this conference was to discuss a complaint submitted by a consumer alleging the failure to fill a prescription properly. The complainant alleged that on or about September 20, 2001 the Registrant dispensed Imipramine 50mg tablets rather than Imipramine 25mg tablets as prescribed while employed at Costco Pharmacy #308, 71 Second Avenue , Waltham, Massachusetts.

Investigator: James C. Emery

Complainant: Not present

Registrant: Ronni Yellen and Counsel, Daniel Wrenn

Costco Pharmacy Manager of Record: Charles Kelley

Costco Pharmacy Representative: Thomas P. Drougais, Regional Supervisor

The Registrant (Yellen) advised the Board that she had previously appeared before the Board with regard to disciplinary action.

Investigator Emery reviewed his report of investigation with the Board.

Yellen acknowledged responsibility for the medication error. Yellen stated that Emery's report seemed accurate.

With regard to pharmacy incident notification, Bob Paone asked Costco Pharmacy representatives which pharmacy staff member spoke with the patient and advised them that the medication was just a different brand? The Costco Pharmacy Manager of Record, Charles Kelley replied that he spoke to the patient about the incident but refutes the complainant's representations. However, Kelley noted that he spoke to the patient about the incident in December of 2001 not October. Kelley suggested that perhaps when the patient picked up a refill prescription on or about October 24, 2001 she spoke to a third pharmacist about the matter who was unfamiliar with the incident.

Yellen informed the Board that she conducted both the prescription data entry and the final product verification. Yellen said that she utilizes an NDC match during the final check process. With regard to corrective measures implemented post incident, Yellen stated that she now keeps all the prescription information and the stock bottle together for reference during final checking procedures.

Yellen said that she first became aware of incident in December of 2001 and the prescriber was notified. Yellen stated that an incident report was filed with Costco pharmacy management.

Tom Drougais, Regional Costco Pharmacy Supervisor, informed the Board that Costco is in the process of rolling out both image technology and workflow enhancements in its Massachusetts pharmacy locations ("Innovative Solutions"). Drougais said that the NDC final check policy is and was in effect at the time of the incident.

A **Motion** was made by Bob Paone to file a complaint against pharmacist Steven Levin for his alleged explanation to the patient regarding the medication error reporting to the pharmacy. Investigator Emery said he spoke to the Registrant (Levin) about the incident and Levin allegedly does not recall either the incident and or a conversation with complainant. Thereafter, a **Motion** was made by Bob Paone to offer the Registrant (Yellen) an Advisory Letter for the failure to fill a prescription properly with stipulations that Yellen 1) file a USP Medication Error Report with USP PRN (a copy to the Board) and 2) complete a two (2) hour home study medication error reduction continuing education program within thirty (30) days following receipt of the agreement. The motion was seconded by Harold Sparr. The motion carried.

A **Motion** was made by Jim DeVita to offer Costco Pharmacy #308, Waltham an Advisory Letter for the failure to fill a prescription properly with stipulations that Costco pharmacy department care of Costco Regional Pharmacy Supervisor, Thomas P. Drougais, shall submit the Board a statement regarding the corrective measures

implemented by Costco to reduce the likelihood of similar medication errors (any such measures may include consideration for the basket method as such relates to prescription processing and final product verification). The motion was seconded by Dan Sullivan. The motion carried.

**9. 2:40 p.m. to 3:20 p.m.**

**Investigative Conference: DS-02-051 & PH-02-059**

**In the matter of CVS Pharmacy #860, 6 Post Office Square, Harwichport, MA 02646 (Permit # 1406) and Registrant, Nancy K. Barsic, R.Ph., (License # 21269).**

The purpose of the conference was to re-discuss a complaint submitted by a consumer alleging the failure to fill a prescription properly. The complainant alleged that on or about August 06, 2001 the Registrant dispensed Seroquel rather than Serzone as prescribed while employed at CVS Pharmacy #860, 6 Post Office Square, Harwichport, Massachusetts. The complaint was initially reviewed by the Board on or about April 23, 2002.

Investigator: James C. Emery

Consumers: Present and Counsel, Ann Marie Maguire

Registrant: Nancy Barsic

CVS former Manager of Record: Lawrence Favreau

CVS current Manager of Record: Annette McAllister

CVS Representatives: CVS Counsel, Barry Jasilli, Charlie Martineau (former Regional Healthcare Manager per incident) and Troy Dobson (CVS District Manager).

**Recused:** Jim DeVita

Investigator Emery reviewed his report of investigation with the Board. Emery stated that on or about 366 prescriptions were processed on the incident date. Emery said that the basket method of prescription processing was utilized by the pharmacy.

Harold Sparr requested that Troy Dobson respond to Barsic and Favreau's assertion that CVS Pharmacy provided inadequate staffing to the Harwichport pharmacy department. Mr. Dobson replied that CVS attempted in good faith to provide adequate staffing coverage to the pharmacy.

Mr. Dobson said that in July through August of 2001 on or about 240 hours of pharmacist overlap coverage were appropriated for the pharmacy and all except for 34 hours were covered. Dobson said that he responded to any telephone call(s) made to him regarding specific requests for pharmacy staffing coverage. Dobson recalled that the incident date was a Monday and a graduate pharmacy student was sent to the pharmacy because an overlap pharmacist was not available for the shift. Dobson said that it is not CVS policy to pull technicians from home stores to cover open shifts in the district unless the on duty pharmacist approves of such action. Dobson said that he

was responsible for the staffing report at the pharmacy specific to the incident. Dobson stipulated that he is not a pharmacist by trade.

Barsic stated that she usually arrived at the pharmacy around 7:30 a.m. prior to the pharmacy's operation hours at 8 a.m. to allow for time to catch up on the previous day(s) workload.

With regard to the staffing roster reviewed with the Board by Troy Dobson, Barsic stated that all the persons identified were cashiers not technicians with the exception of "Mary Beth". For reference, Barsic stated that "Mildred" was a cashier at the time of the incident but subsequently became a CVS "PSA" certified technician.

Jasilli informed the Board that CVS has 3 types of pharmacy supportive personnel; a lead technician, a pharmacy technician and a "PSA" technician.

Barsic stated that on the incident date, a graduate pharmacy student worked in the pharmacy beginning a shift around 9 a.m.

McAllister informed the Board that the average pharmacy staffing in Harwichport on Mondays is 1 pharmacist, 1 overlap pharmacist, and 2 technicians. McAllister stated that the pharmacy fills on average about 1450 prescriptions weekly in the summer.

The counsel for the complainant stated that the patient has not yet recovered from a stroke.

The complainant's brother stated that his family is concerned about the quality of help made available to the Harwichport CVS Pharmacy.

Mr. Martineau stated that the pharmacy department has a good track record with regard to quality performance. Martineau said that he recalled only 1 telephone call from former Manager Favreau about concerns related to staffing concerns.

In addition, Martineau stated that pharmacy technician staffing hours were not reduced but rather were increased. Martineau commented that the pharmacy did institute red shelf dividers in the pharmacy for the top 50 possible medication errors. Martineau said that he did not appreciate the full gravity of apparent staffing concerns until hearing related testimony today.

Barry Jasilli provided the Board with an overview of the CVS technician training program (9 modules of training). Jasilli stated that both the CVS EPIC software system and high-risk medication error quality assurance procedures were in place at the pharmacy at the time of the incident.

Annette McAllister stated that when she became Manager of Record at Harwichport, the pharmacy was improved by means of a renovation and workflow procedures were

already in place to include prescription prioritization and pharmacist final checking. McAllister said that the pharmacy staff works well together with 1 staff pharmacist, a 2<sup>nd</sup> overlap pharmacist and a technician who can data process prescriptions. McAllister stipulated that the pharmacy strives to allow the checking and or verification pharmacist to work uninterrupted.

Troy Dobson provided the Board with a master's pharmacy staffing list specific to the Harwichport pharmacy for reference.

Former CVS Manager of Record, Favreau commented that the CVS EPIC software system is only good provided the pharmacy is staffed with competent help.

Mr. Martineau stated that according to pharmacy software records, the prescription at issue was filled on or about 7:55 a.m.. In addition, Martineau represented that between 7 and 8 a.m. two (2) prescriptions were processed and from 8 to 9 a.m. approx. thirty (30) prescriptions were processed but not necessarily checked.

Barsic advised the Board that she conducted the final check and or verification of the prescription at issue.

A **Motion** was made by Harold Sparr to take the matter under advisement, the motion was seconded by Donna Horn. The motion carried.

**10. 3:20 p.m. to 4:10 p.m.**

**Investigative Conference: DS-02-016 & PH-02-066**

**In the matter of J.E. Pierce Apothecary Inc., 1180 Beacon Street, Brookline, MA 02446 (Permit # 1297) and Registrant, Stephen L. Grossman, R.Ph., (License # 18342).**

The purpose of the conference was to discuss a complaint submitted by a hospital Director of Pharmacy describing circumstances allegedly related to the July 23, 2001 dispensing of a prescription for 4-Aminopyridine 10mg capsules. The complaint alleged that on or about July 25, 2001 a patient was admitted to the hospital with symptoms possibly related to an improperly compounded prescription by the Registrant for 4-Aminopyridine while employed at J.E. Pierce Apothecary Inc., 1180 Beacon Street, Brookline, Massachusetts.

Investigator: Alan Van Tassel

Complainant: Present (husband and wife) and Counsel, Mary Diauro

Registrant: Stephen L. Grossman & Counsel, Jeffrey Smith

Sturdy Memorial Hospital Representative: Andrew Metters, Director of Pharmacy

The Registrant (Grossman) advised the Board that he had previously appeared before the Board with regard to a prescription labeling and or records issue.

Investigator Alan Van Tassel reviewed his report of investigation with the Board.

Mr. Grossman stated that the report seemed accurate as read by the investigator.

Andrew Metters, Director of Pharmacy for Sturdy Memorial Hospital, stated that he filed the complaint with the Board. Metters commented that he was not privileged to information regard the status of the related FDA investigation.

Investigator Van Tassel stated that the FDA matter was an open investigation and any findings made to date were not public information. Van Tassel said that the medication at issue was not under Board possession to review but rather a sample of such was being tested by both the hospital and FDA.

Grossman stated that traditionally when a refill request is generated at the pharmacy for a compounded medication the related prescription label is cross-referenced by the technician against the compounding formula for dispensing purposes. Following compounding by the student, the pharmacist verifies the final product for quality assurance purposes. However, if a new prescription for a compounded medication is presented to the pharmacy then a pharmacy student creates a new compounding formula which is to be verified by the on duty pharmacist.

Grossman acknowledged responsibility for the medication error. Grossman stated that his initials were on the compounded prescription at issue. Grossman said that he did not recall pulling the drug used for compounding for verification reference purposes in this case. Grossman stated that 100 capsules of medication were compounded for the patient but he does not know whether the medication was actually compounded the same day or day after the prescription label was generated.

Grossman advised the Board that all supportive personnel who assist him with compounding in the pharmacy are pharmacy students with the local colleges of pharmacy.

Grossman responded to the Board that no other patients received medication from the compounded batch at issue.

With regard to corrective measures implemented following the incident, Grossman said that in addition to final checking and or verification procedures; 1) all medication recipes are reviewed and initialed in the manufacturing log book by the pharmacist on duty, 2) the original stock bottle used for compounding is verified by pharmacist on duty and 3) new technology has been added to the pharmacy in the format of an electronic scale that records the amount of medication weighed.

Grossman informed the Board that the pharmacy student who compounded the medication at issue under his supervision worked for the pharmacy for about 4

months. Grossman said that he did not follow up with the student about the incident because the student took ill and left college.

Grossman advised the Board that the recipe for compounded medication at issue was not produced by PCCA but rather by was his unique pharmacy formula. However, Grossman stated that the drug used to compound the formula was obtained from PCCA. According to Grossman, PCCA did not have a recipe for the compounded medication on file.

Grossman indicated that he was aware of the toxic nature of the compounded medication. However, Grossman stated that the possible benefit of the medication to the patient justified the inherent risks provided the medication was compounded correctly.

A **Motion** was made by Harold Sparr to take the matter under advisement. The motion was seconded by Jim DeVita. The motion carried.

**11. 4:10 p.m. to 4:45 p.m.**

**Administrative Business Items:**

A) In the matter of PH-90-038, Registrant Robert H. Giovannucci Licensure Number 16257, Expiration Date 12/31/2002: request for removal of probation (conditional documentation outlined in the consent agreement was previously submitted to the Board: compliant)

Vote: Approved:   X   Denied:       

A **Motion** was made by Karen Ryle to approve the Registrant's request for removal of probation. The motion was seconded by Bob Paone. Vote: In Support: Bob Paone, Jim DeVita, Marilyn Barron, Karen Ryle, Harold Sparr, Dan Sullivan, Opposed: Donna Horn. The motion carried.

B) Board review of pharmacy technician training programs and or pharmacy technician assessment examinations. The Board reviewed related examinations.

Dr. Paone provided the Board with an overview of the pharmacy technician training programs and pharmacy technician assessment examinations review process. Dr. Paone distributed the Board a handout specific to his review of the below-referenced programs and examinations.

1) **Fallon Clinic:** The Board did not approve either the training program or the assessment examination were approved by the Board. The Board requested additional information from Fallon Clinic to include additional examination questions and additional training program topics.

2) **NACDS:** A **Motion** was made by Bob Paone to approve the pharmacy technician training program. The motion was seconded by Jim DeVita. The motion carried.

A Motion was made by Bob Paone to approve the pharmacy technician assessment examination with the addition of questions covering the knowledge-based areas of : (1) practice settings; (2) patient confidentiality; and (3) storage requirements (See Board regulation 247 CMR 8.02(1)(a)6.) In addition, the Board requested that NACDS insure that correct answers to examination questions NOT appear indented but all answer options be listed uniformly. The motion was seconded by Harold Sparr. The motion carried.

3) **The Jim Viera / Stanley Rome Program:** The Board did not approve either the training program and or the assessment examination. The Board requested additional information from the parties to include training program topics of pharmacy security, medical abbreviations, product selection and final checking by pharmacists. In addition, the Board requested storage requirement examination questions and the need for multiple choice examination questions in the A-E format rather than A-D.

4) **New England Sinai Hospital and Rehab. Center:** The Board did not approve the assessment examination. The Board requested additional information from New England Sinai Hospital to include routes of administration questions and the need for multiple choice examination questions (A-E) rather than true / false questions.

C) Grand Rounds Presentation (Hospital / Industry Consortium): June 12, 2002 for discussion (no handout). The Board discussed final arrangements for the above-referenced CE program.

D) Continuing Education Committee review of Board CE program requests for approval: for related review and discussion. Harold Sparr updated the Board with regard to review of related CE programs.

E) DRAFT File Review Document: for discussion. The Board reviewed a draft of a document to be used during complaint committee file review.

F) Minutes for December 18, 2001:     approve \_\_\_\_ amend \_\_\_\_

Vote: Tabled.

Minutes for January 08, 2002:     approve \_\_\_\_ amend \_\_\_\_

Vote: Tabled.

Minutes for January 22, 2002:     approve \_\_\_\_ amend \_\_\_\_

Vote: Tabled.

Minutes for February 05, 2002:    approve \_\_\_\_ amend \_\_\_\_

Vote: Tabled.

G) The Board advised Board staff to place the OxyContin® matter on the June 11, 2002 Agenda for related discussion and vote.

H) The Board advised Board staff to place the CVS Pharmacy #860, Harwich Port matter on the June 11, 2002 Agenda for related discussion and vote. (DS-02-051 & PH-02-059)

I) The Board advised Board staff to place the Lynn Community Health Center 340B Program matter on the June 11, 2002 Agenda for related discussion and vote.

J) Potassium Iodide dosing demonstration: Dr. Paone reviewed the Potassium Iodide FDA dosing guidelines with the Board. Thereafter, the Board manually reduced the KI tablets to the dosages recommended for both children and infants. The Board consensus was that it was very difficult to break the ½ KI tablets in ½ a second time. Bob Paone stated that Anbex was currently studying the flavoring issue related to the dissolving of KI tablets. Dr. Paone said that Anbex was willing to with the Board and DPH on public service campaigns.

Adele Audet stated that DPH Asst. Commissioner Nancy Ridley requested that pharmacies to be involved with plans to distribute KI and to counsel the public regarding appropriate dosing. Chuck Young advised the Board that he had concerns for patient health literacy as such related to pharmacist's role in KI distribution.

**12. 4:45 p.m.**

A Motion was made by Harold Sparr to adjourn the meeting. The motion was seconded by Bob Paone. The motion carried. Meeting Adjourned.

Respectfully submitted by:  7/12/02  
Executive Director Date -  
  
Printed Name

Reviewed by counsel: June 08, 2002  
Draft approved: June 08, 2002  
Board adopted: June 09, 2002

**Executive Session Board Minutes  
May 28, 2002**

**2. 9:50 a.m. to 10:10 a.m.**

**In the matter of David L. Lambert, Registrant (License Number 22821 /  
Expiration on or about 12/31/1996).**

A **Motion** was made by Donna Horn to discuss the matter with the Registrant (Lambert) in executive session. The motion was seconded by Bob Paone. The motion carried unanimously.

Chuck Young provided the Board with an overview of the reinstatement request. According to Mr. Young the Registrant needed to produce evidence of compliant continuing education (CE) for calendar years 1997 & 1998. Board records indicate that 45 CE penalty hours were due for 1997 CE deficiencies. Mr. Young suggested that prior to 2002, Mr. Lambert last contacted the Board in writing on or about October of 2001. It should be noted that Lambert's CE were complaint for calendar years 1999, 2000 & 2001.

The Registrant (Lambert) advised the Board that he completed the 45 CE penalty hours and submitted copies of such to the Board on or about December of 1999 or January of 2000. However, the Registrant stated that he failed to follow up with the Board following related submission.

The Registrant stated that he initiated the reinstatement process again with the Board on or about March of 2002 during related conversation with James D. Coffey. Lambert said that he contacted both MCPHS and Northeastern School of Pharmacy to obtain duplicate certificates of CE completion. To date, Lambert stipulated that he is still waiting for Northeastern to respond to his request for CE records.

Dr. Paone asked Mr. Sharp to clarify his letter to the Board wherein he suggested that Lambert was in good standing with CVS. Mr. Sharp advised the Board that he was not aware the Mr. Lambert was not licensed with the Board. Furthermore, Sharp stated that following each pharmacist renewal period, CVS requests a copy of each pharmacists wallet registration cards as a means for license verification. Sharp suggested that Lambert matter just slipped by the wayside.

Donna Horn suggested that according to the documentation at hand, Mr. Lambert allegedly worked without a current license for on or about 3 to 4 years.

The Registrant stated that on or about March of 2002 he started a new position with CVS as a Regional Healthcare Manager. Lambert said that in such position he does not work behind the bench as a dispensing pharmacist.

Donna Horn stated that Mr. Lambert's recent CE's were compliant with the exception

of CE's for 1997 & 1998.

Mr. Lambert informed the Board that he needed more time to produce the CE records at issue.

Harold Sparr advised the Registrant to contact Dean Robinson at Northeastern University to obtain duplicate copies of continuing education certificates. Mr. Sparr informed the Registrant that he had 30 days to produce the Board requested CE records. Sparr said that upon Board receipt of the records the Registrant could appear before the Board again to discuss the matter.

**A Motion** was made by Harold Sparr to move out of executive session. The motion was seconded by Donna Horn. The motion carried unanimously.